

LIBELED: 6-19-58, S. Dist. N.Y.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess since the article contained less vitamin B₁ and less niacinamide than declared; 502(a)—the label statement "Each containing * * * Thiamin hydrochloride (B₁) 3.0 mgs. * * * Niacinamide 30.0 mgs." was false and misleading as applied to a product containing less than the declared amounts of thiamin hydrochloride and niacinamide, and the label statement "Caution: To be dispensed only by or on the prescription of a physician" was false and misleading as applied to a product that was not restricted to dispensing on a physician's prescription; and 502(f) (1)—the labeling of the article failed to bear adequate directions for use since no dosage statement was given and no indications for use were stated.

DISPOSITION: 7-18-58. Default—destruction.

5712. Creme ointment and suntan lotions. (F.D.C. No. 41902. S. Nos. 1-480/1 P.)

QUANTITY: 2,204 ctns. of *creme ointment*, 643 6-oz. btls.; and 242 4-oz. btls., and 27 combination sets of *suntan lotions* at Fort Lauderdale, Fla., in possession of Aloe Creme Laboratories, Inc.

SHIPPED: 1-29-58, from Milwaukee, Wis., by Kolmar Laboratories, Inc.

LABEL IN PART: (Ctn.) "Alo-Creme With Lanolin Ointment * * * Ingredients: Contains 50% or more fresh "gel" from the Aloe Vera leaf, protected in a specially prepared base containing lanolin. Contains no anaesthetic drugs. Distributed by Aloe Creme Laboratories, Inc., Ft. Lauderdale, Florida"; (btl.) "Fashion Tan by Aloe Creme * * * Contains the "gel" of Florida's famous Aloe Vera plant"; (btl.) "After Tan by Aloe Creme * * * contains the "gel" of Florida's famous Aloe Vera Plant in a super rich lanolin base."

ACCOMPANYING LABELING: Leaflets entitled "Sunburn vs. Suntan" and "Aloe-Creme Ointment."

RESULTS OF INVESTIGATION: The leaflets entitled "Aloe-Creme Ointment" and the ctns. for the ointment were prepared locally.

LIBELED: 7-21-58, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the labeling of the ointment contained false and misleading representation that the article was an adequate and effective treatment for all burns, skin abrasions, cuts, rashes, itching, dermatitis, skin irritations, hemorrhoids, piles, and bed sores; and 502(f) (2)—the ointment was offered for piles and hemorrhoids, and its labeling failed to bear a warning that the article should not be used in case of rectal bleeding.

502(a)—when shipped and while held for sale, the labeling which accompanied the suntan lotions contained false and misleading representations that the articles were an adequate and effective treatment for preventing skin cancer.

DISPOSITION: 11-18-58. Consent—claimed by Aloe Creme Laboratories, Inc., and relabeled.

5713. Medicated cream, inhalant and rubbing oil, and castile soap. (F.D.C. No. 41849. S. Nos. 19-177/9 P.)